UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

TYLER WOOD,

Plaintiff,

DECISION AND ORDER

-vs-

14-CV-6298 CJS

MEDTRONIC, INC.,

Defendant.

INTRODUCTION

This is a products liability action involving the medical "bone graft" product "InFUSE," which is manufactured by Medtronic, Inc. ("Defendant"). The U.S. Food and Drug Administration ("FDA") approved the sale of InFuse, for use in certain lumbar-spine surgical procedures, through a process known as premarket approval ("PMA"). Tyler Wood ("Plaintiff") maintains that he was injured when his surgeon used InFuse "off label" to repair his cervical spine. Now before the Court is Defendant's motion (Docket No. [#10]) to dismiss the Complaint. The application is granted, and this action is dismissed with prejudice.

PROCEDURAL HISTORY

On April 25, 2014, Plaintiff commenced this action in New York State Supreme Court, Monroe County, with the filing of a two-page Complaint, consisting of eleven paragraphs.[1] The Complaint indicates that Plaintiff is a resident of New York, and that Defendant is a corporate resident of Minnesota. The Complaint asserts that Defendant engaged in "negligence and other culpable acts," which injured Plaintiff. More specifically, the Complaint asserts that "on or about March 14, 2006," "Plaintiff underwent a cervical spine

[1]The Complaint was filed one day shy of Plaintiff's twenty-first birthday.

procedure [in which Defendant's InFUSE] bone graft was used," and that the bone graft "caused injuries to the Plaintiff which are severe and permanent." (Complaint [#1] at ¶¶ 6-7). As for the alleged wrongdoing by Defendant, the Complaint asserts that Defendant committed the following acts: 1) it "encouraged the medical industry" to use [InFUSE] in cervical spine surgery, even though the bone graft was not "designed or approved" by the FDA for use in the cervical spine; 2) it "defectively designed and manufactured" InFUSE; and 3) it "failed to warn" about the dangers of using InFUSE "off label" for cervical spine surgery. The Complaint, though, does not explain the nature of Plaintiff's injury or how Defendant encouraged the medical industry to misuse InFUSE. Nor does the Complaint identify the particular "dangers" of using InFUSE in the cervical spine, about which Defendant allegedly failed to warn. The Complaint also does not identify any particular design defect or manufacturing defect.

On May 30, 2014, Defendant removed the action to this Court, asserting that there was complete diversity between the parties, and that the amount in controversy likely exceeds $75,000.00. Subsequently, there was no activity in the action for five months. On November 10, 2014, the Court issued an Order [#5], directing Plaintiff to show cause why the action should not be dismissed for failure to prosecute. On November 25, 2014, Plaintiff responded, and provided additional information regarding his claim. More specifically, Plaintiff indicated that in 2001, when he was eight years of age, he fell off a toy vehicle, known as a "power wheel," and sustained injuries to his neck, at the C1-C2 level, requiring the implantation of a surgical rod in his spine.[2] Plaintiff further explained that the metal rod

[2]Plaintiff indicated that he is pursuing a separate products liability action in New York State Supreme Court, against the manufacturer of the power wheel.

eventually fractured, and that on March 14, 2006, when he was twelve years of age, he had corrective surgery which included the implantation of InFUSE in his cervical spine.[3] Plaintiff asserts that subsequently, he "has experienced symptoms which are believed to be related to the use of [InFUSE]." The Court declined to dismiss the action for failure to prosecute.

On January 30, 2015, Defendant filed the subject motion pursuant to Fed.R.Civ.P. 12(b)(6) to dismiss the Complaint, on the following grounds: 1) InFUSE's design, manufacture and labeling were approved by the FDA, and Plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a); 2) there is no prohibition on using medical devices "off label," and, in any event, the Complaint fails to plausibly plead that Defendant encouraged the off-label use of InFUSE for cervical spine applications, or that any such encouragement proximately led to the surgeon's decision to use InFUSE when operating on Plaintiff's neck; and 3) Plaintiff's claims are barred by "a variety of state-law grounds," including the lack of a duty-to-warn, the bar against strict-liability claims for "unavoidably unsafe" products such as medical devices, and disclaimer of warranties.

On February 12, 2015, the Court issued a Motion Scheduling Order [#11], directing Plaintiff to file and serve any opposing papers by March 13, 2015. Plaintiff did not serve any opposing papers by that date, and on April 3, 2015, Defendant filed a reply, advising the Court that Plaintiff had failed to respond. The same day, the Court received a one-line faxed letter request from Plaintiff, stating: "In connection with the above mentioned matter, I am respectfully requesting an extension of time to respond to the Defendant's Motion to dismiss

[3]Such fact is curious to the Court, since InFUSE's warning label expressly indicates that it is intended for "skeletally mature patients."

Plaintiff's Complaint." On April 7, 2015, the Court contacted Plaintiff's counsel by email and requested that he tell the Court how much additional time he was seeking. In that regard, the Court was inclined to grant Plaintiff's request because it routinely does so when litigants ask for extensions *prior to a filing deadline*. Moreover, the Court at that time had not yet seen Defendant's reply or reviewed the docket sheet, and therefore did not realize that Plaintiff's filing deadline had already passed. In any event, it was not until almost a month later, on April 30, 2015, that the Court received a further communication from Plaintiff, asking that the deadline for responsive papers be extended, until May 6, 2005. Plaintiff, though, did not explain why he had failed to comply with the Motion Scheduling Order. Then, on May 8, 2015, Plaintiff, without having received a ruling from the Court, filed a response [#13] to Defendant's motion, including a motion to amend the Complaint.

On May 18, 2015, having reviewed the docket sheet, the Court issued a Decision and Order [#15], denying Plaintiff's request for an extension of time, and indicating that the Court would *not* consider his opposing papers or motion to amend, because he had not offered any good cause for failing to comply with the Motion Scheduling Order. *See*, Decision and Order [#15] (Observing that Plaintiff offered "no reason whatsoever" for failing to comply with the Motion Scheduling Order).

While the Court consequently considers Defendant's motion to be unopposed, it nevertheless observes that Plaintiff's untimely opposition papers and cross-motion assert claims that were not contained in the original Complaint. For example, whereas the original Complaint [#1] alleges that Plaintiff's injury was related to Defendant "encourag[ing] the medical industry to use the bone graft off-label in cervical spine procedures," he now claims that he "does not predicate his claims on off-label promotion," but instead, maintains that his

claims are actually based on Defendant's alleged "fraudulent misrepresentations" made in connection with the FDA approval process. More specifically, the proposed Amended Complaint contends that Defendant became aware, either before or after the FDA approved InFUSE, that using InFUSE in the cervical spine would have "extreme adverse effects," but hid that information from the FDA,[4] and, further, that despite having such knowledge, Defendant made improper payments to doctors to induce them to promote the use of InFUSE in the cervical spine.

The Court observes, however, that such allegations are entirely conclusory, in that they fail to allege any particulars, such as what information Defendant allegedly withheld from the FDA. There are simply no plausible factual allegations that Defendant knew that InFUSE was unsafe for use in the cervical spine, but promoted it for such use anyway.[5] Indeed, there are no plausible factual allegations that InFUSE is actually unsafe for off-label use in the cervical spine at all.

On September 10, 2015, counsel for the parties appeared before the undersigned for oral argument. After a discussion with counsel about various issues, the Court indicated that it intended to grant the motion to dismiss the Complaint [#1], but welcomed argument as to whether such dismissal should be with prejudice or without prejudice. Defendant's counsel averred that dismissal should be with prejudice, since even the claims in the proposed Amended Complaint lacked merit.[6] Whereupon the Court asked Plaintiff's counsel

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[4] *See*, 21 U.S.C. § 360e.

[5] See, Proposed Amended Complaint at ¶ ¶ 23, 43-44, 54, 55(c)

[6] Defendant acknowledged that it had asked the Court not to consider Plaintiff's Motion to Amend, and that the Court had ruled that it would not consider them, but nevertheless contends that the Court should consider the proposed pleading in deciding whether to dismiss with prejudice.

how he might proceed if the Court were to dismiss the action without prejudice. In response, Plaintiff's counsel candidly acknowledged that he did not think he could proceed further with the action, since, notwithstanding what was alleged in the proposed amended pleading, he had no factual basis for asserting either that Defendant had withheld information from the FDA or that a manufacturing defect existed.

DISCUSSION

Motions to Dismiss Pursuant to FRCP 12(b)(6)

The general legal principles concerning motions under FRCP 12(b)(6) are well settled:

> Federal Rule of Civil Procedure 8(a)(2) requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the claim is and the grounds upon which it rests. While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 1964–65, 167 L.Ed.2d 929 (2007); *see also, ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) ("To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.' ") (*quoting Bell Atl. Corp. v. Twombly*) (footnote omitted).

When applying this "plausibility standard," the Court is guided by "two working principles":

> First, although a court must accept as true all of the allegations contained in a complaint,[7] that tenet is inapplicable to legal conclusions, and threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss, and determining whether a complaint states a plausible claim for relief will be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.

Harris v. Mills, 572 F.3d 66, 72 (2d Cir. 2009) (citations and internal quotation marks omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679, 129 S.Ct. 1937, 1950 (2009) (citation omitted). "The application of this 'plausibility' standard to particular cases is 'context-specific,' and requires assessing the allegations of the complaint as a whole." *Pension Ben. Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Retirement Plan v. Morgan Stanley Inv. Management Inc.*, 712 F.3d 705, 719 (2d Cir. 2013) (citation and internal quotation marks omitted).

Applying these principles to the instant action, the Court finds at the outset that to the extent the Complaint [#1] is attempting to assert claims for design defect or failure to warn based on standards that go beyond what the FDA imposed, such claims are preempted by 21 U.S.C. § 360k(a). *See, Otis-Wisher v. Medtronic, Inc.*, — Fed.Appx. — , 2015 WL 3557011 at *2 (2d Cir. Jun. 9, 2015) ("Plaintiff's claims for strict liability failure to warn, strict liability design defect, and negligent failure to warn all seek to impose safety-related

[7]The Court must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party. *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir.1999), *cert. den.* 531 U.S. 1052, 121 S.Ct. 657 (2000).

requirements on the device or its labeling beyond those imposed by the FDA. Accordingly, these claims are expressly preempted under § 360k(a).") (citation omitted). To the extent that Plaintiff is attempting to assert a manufacturing defect claim and fraud claim, such claims must also fail, because they are conclusory and therefore not adequately pleaded.[8] Further, Plaintiff now admits that he is not aware of any factual basis for such claims, and cannot articulate any theory upon which he could proceed, within the parameters of Rule 11, if he were allowed to amend. Accordingly, the Court finds that this action must be dismissed with prejudice. *See*, *Cortec Industries, Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991) (Indicating that in the 12(b)(6) context, a complaint should be dismissed with prejudice where it is apparent that the "plaintiff is unable to allege any facts sufficient to support its claim.").

CONCLUSION

Defendants' application to dismiss [#10] is granted and this action is dismissed with prejudice.

So Ordered.

Dated: Rochester, New York
October 2, 2015

ENTER:

/s/ Charles J. Siragusa
CHARLES J. SIRAGUSA
United States District Judge

[8] *See, Otis-Wisher v. Medtronic, Inc.*, 2015 WL 3557011 at *2 (Affirming dismissal of manufacturing defect claim that was "wholly conclusory" and of fraud claim that was not pleaded with particularity as required by Fed.R.Civ.P. 9(b)).